UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

LESLIE M. GREENWOOD,

Plaintiff,

v.

DECISION AND ORDER

21-CV-1101S

ARTHREX, INC.,
TE CONNECTIVITY CORPORATION f/k/a HEAT SHRINK INNOVATIONS, LLC, and PRECISON EDGE SURGICAL PRODUCTS COMPANY, LLC,

Defendants.

I. Introduction

This is a removed diversity action wherein Plaintiff Leslie Greenwood alleges product liability against Defendant Arthrex, Inc. ("Arthrex"), a medical device manufacturer. Arthrex produced the "Arthrex Burr," a medical device that purportedly burned Plaintiff during her October 2018 surgery.

Plaintiff amended her Complaint multiple times (Docket Nos. 13, 46, 49) following Motions to Dismiss or for Judgment on the Pleadings by Defendants (Docket Nos. 18, 20, 37), see Greenwood v. Arthrex, Inc., No. 21CV1101, 2022 WL 2117763 (W.D.N.Y. June 13, 2022) (Skretny, J.) (Docket No. 31) ("Greenwood June 2022 Decision"); Greenwood v. Arthrex, Inc., No. 21CV1101, 2023 WL 2457070 (W.D.N.Y. Mar. 10, 2023) (Skretny, J.) (Docket No. 48) ("Greenwood March 2023 Decision"), and her Cross-Motion for Leave to Amend the Complaint (Docket No. 41). Familiarity with these prior Decisions is presumed.

Presently is her Fourth Amended Complaint (Docket No. 49). In response, Arthrex moved to dismiss (Docket No. 51[1]), with prejudice. For the reasons stated below, Arthrex's Motion (Docket No. 51) is granted.

II. Background

A. Procedural History

Leslie Greenwood originally sued Arthrex in New York State Supreme Court (Docket No. 1, Notice of Removal ¶ 2, Ex. A, Tab 1) and Arthrex answered (id., Ex. A, Tab 3). Greenwood then amended that Complaint adding Defendants Precision Edge Surgical Products Company ("Precision Edge") and TE Connectivity Corporation ("TE") (id. ¶ 5, Ex. A, Tab 7). Precision Edge removed this case to this Court (id. ¶ 9, Exs. B, C), TE and Precision Edge then moved to dismiss the Amended Complaint (Docket Nos. 6, 7) but that Motion was dismissed as moot after Greenwood filed her Second Amended Complaint (Docket No. 17; see 2d Am. Compl., Docket No. 13). Meanwhile, Arthrex answered the Second Amended Complaint (Docket No. 19).

TE (Docket No. 18) and Precision Edge (Docket No. 20) then moved to dismiss the Second Amended Complaint. On June 13, 2022, this Court granted their Motions, Greenwood June 2022 Decision, supra, 2022 WL 2117763 (Docket No. 31), dismissing with prejudice Greenwood's strict product liability theories, negligence, and breach of warranties claims against TE, id. at *9-13, 14, and against Precision Edge, id. at *6-9, 14.

[1]In support of its Motion, Arthrex submits its Memorandum of Law, Docket No. 51, and its Reply Memorandum, Docket No. 55. Arthrex later filed Notice, Docket No. 53, of its withdrawal of its arguments against the First Cause of Action.

In opposition, Plaintiff submits her Memorandum of Law, Docket No. 54.

On July 8, 2022, Arthrex moved for Judgment on the Pleadings (Docket No. 37). Greenwood cross-moved for leave to amend her Second Amended Complaint (Docket No. 41). On January 3, 2023, this Court deferred ruling on Arthrex's Motion, granted leave to amend (Docket No. 45), and on January 9, 2023, Greenwood filed her Third Amended Complaint (Docket No. 46). The Third Amended Complaint removed allegations against TE and Precision Edge and alleged four modified Causes of Action against Arthrex for negligence, strict products liability, breach of warranties, and failure to warn (see generally id.).

On March 10, 2023, this Court granted in part Arthrex's Motion for Judgment on the Pleadings in that Third Amended Complaint, dismissing with prejudice Greenwood's Third Cause of Action but not dismissing the other causes of action while granting Greenwood leave yet again to amend the Complaint, Greenwood March 2023 Decision, supra, 2023 WL 2457070, at *11-12. There, this Court concluded that Greenwood needed to amend her defective manufacturing and breach of a duty to warn claims, while finding that her defective design claim did not require amendment, id. at *6-7, 10-11.

B. Fourth Amended Complaint (Docket No. 49)

As previously discussed, id. at *2, Greenwood was injured during a surgical procedure on or about October 25, 2018, from the use of an Arthrex Burr device resulting in permanent and serious injuries to her (Docket No. 49, 4th Am. Compl. ¶¶ 10-11). Greenwood's doctor later told her that there had been a "mechanical malfunction of the Arthrex surgical instrument identified by the manufacturer that resulted in a significant heating of the shaft of the burr that was most likely the cause of the anterior thermal on her shoulder" (id. ¶ 12).

As previously amended, the First Cause of Action alleges Arthrex's negligence in manufacturing and distributing the Arthrex Burr device (id. ¶¶ 6-9, 11), contending that the Arthrex Burr device was defective "because it generated an unsafe and dangerous amount of heat and it proximately caused Plaintiff to suffer serious personal injuries, including a severe burn to the skin of her shoulder" (id. ¶ 13).

The Second Cause of Action (as amended in prior iterations of the pleadings) alleges that Arthrex defectively designed and manufactured its Arthrex Burr device, negligently putting the device into the stream of commerce (id. ¶¶ 22, 24, 28, 31). Greenwood claims that it was feasible for Arthrex to design a safer alternative to the Arthrex Burr device (id. ¶¶ 29-30), without however proffering a safer design. She again invokes the recall statement issued 90 days after her surgery (id. ¶ 30). She claims that the defective device overheated and burned her because Arthrex failed to conduct adequate heat testing or failed to use proper alloys and insulation in the device to prevent overheating (id. ¶ 32).

The Fourth Amended Complaint omits the former Third Cause of Action for breaches of warranties. Instead, the amended Third Cause of Action repeats claims formerly alleged in the Fourth Cause of Action of prior versions of the pleading (cf. Docket No. 46, 3d Am. Compl. ¶¶ 43-47) for failure to warn. There, the Fourth Amended Complaint now alleges that Arthrex failed to warn of the defects that it would cause overheating (Docket No. 49, 4th Am. Compl. ¶¶ 36-41). Greenwood claims that, upon information and belief, that Arthrex's warnings were inadequate or defective because they failed to "include any content indicating that the shaft of the device could generate excessive heat during normal use, causing serious burns" (id. ¶ 39). She claims that

Arthrex's instructions were inadequate or defective, contending that (if they existed) these instructions were not sufficiently prominent, that they were ambiguous or vague, not provided with the device, and/or were otherwise defective (id. ¶ 38). Greenwood now alleges that the cutting of bones and flesh during surgery, as was performed on her, "inherently causes friction and the potential for overheating of the Burr device" (id. ¶ 40).

C. Arthrex's Motion (Docket No. 51) to Dismiss the Fourth Amended Complaint

Arthrex now moves to dismiss the Fourth Amended Complaint (Docket No. 51) with prejudice the remaining three causes of action. After withdrawal of its arguments opposing the First Cause of Action (Docket No. 53), Arthrex now argues that Greenwood still fails to allege either a manufacturing or design defect claim, thus her amended Second Cause of Action should be dismissed (Docket No. 51, Def. Memo. at 4-9). Finally, Arthrex asserts that Plaintiff has not alleged a failure to warn claim in her newly amended Third Cause of Action, either an insufficient warning or the absence of any warning (id. at 9-16).

III. Discussion

A. Motion to Dismiss, Rule 12(b)(6)

As discussed with TE and Precision Edge's Motions, Greenwood June 2022 Decision, 2022 WL 2117763, at *3, under Federal Rule of Civil Procedure 12(b)(6), this Court cannot dismiss a Complaint unless it appears "beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Conley v. Gibson, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957); Greenwood June 2022 Decision, supra, 2022 WL 2117763, at *3. As the Supreme Court held in Bell Atlantic Corp. v. Twombly, 550 U.S. 554, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), a Complaint

must be dismissed if it does not plead "enough facts to state a claim to relief that is plausible on its face," id. at 570.

To survive a motion to dismiss, the factual allegations in the Complaint "must be enough to raise a right to relief above the speculative level," Twombly, supra, 550 U.S. at 555; see Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009). A Rule 12(b)(6) motion is addressed to the face of the pleading. The pleading is deemed to include any document attached to it as an exhibit, Fed. R. Civ. P. 10(c), or any document incorporated in it by reference, Goldman v. Belden, 754 F.2d 1059 (2d Cir. 1985).

In considering such a motion, the Court must accept as true all the well pleaded facts alleged in the Complaint, Bloor v. Carro, Spanbock, Londin, Rodman & Fass, 754 F.2d 57 (2d Cir. 1985). However, conclusory allegations that merely state the general legal conclusions necessary to prevail on the merits and are unsupported by factual averments will not be accepted as true. New York State Teamsters Council Health and Hosp. Fund v. Centrus Pharmacy Solutions, 235 F. Supp. 2d 123 (N.D.N.Y. 2002).

B. Choice of Law

Again as previously observed, Greenwood March 2023 Decision, supra, 2023 WL 2457070, at *4; Greenwood June 2022 Decision, supra, 2022 WL 2117763, at *3-4, New York choice of law procedures are applicable, thus New York substantive law applies here.

C. Legal Standards: Product Liability under New York Law

In granting Arthrex's earlier Motion for Judgment on the Pleadings, this Court discussed the standards under New York law applicable for the various alleged theories

for product liability: strict liability, negligence, and breach of warranty, Greenwood March 2023 Decision, supra, 2023 WL 2457070, at *4-5; see Greenwood June 2022 Decision, supra, 2022 WL 2117763, at *9.

As for a strict liability theory, New York law furthermore recognizes three theories for product defect: defective design, defective manufacturing, and failure-to-warn, Zsa Jewels, Inc. v. BMW of N. Am., LLC, 419 F. Supp. 3d 490, 506 (E.D.N.Y. 2019); Thomas v. ConAgra Foods, Inc., No. 20CV6239, 2021 WL 1176011, at *2 (W.D.N.Y. Mar. 29, 2021) (Wolford, C.J.). Also under New York law, "the elements of negligence claims based on design defect, manufacturing defect, and failure to warn theories are the same as those under strict liability," Miccio v. ConAgra Foods Inc., 224 F. Supp. 3d 200, 208 (W.D.N.Y. 2016) (Wolford, J.); Greenwood June 2022 Decision, supra, 2022 WL 2117763, at *13 (see Docket No. 37, Arthrex Memo. at 9).

"'To state a claim for manufacturing defect under theories of strict liability, negligence, or breach of warranty, the plaintiff must allege that (1) the product was defective due to error in the manufacturing process and (2) the defect was the proximate cause of plaintiff's injury,'" Miccio, supra, 224 F. Supp. 3d at 204 (denying motion to dismiss) (quoting Williamson v. Stryker Corp., No. 12 Civ. 7083(CM), 2013 WL 3833081, at *4 (S.D.N.Y. July 23, 2013) (citation omitted)) (Docket No. 37, Arthrex Memo. at 4). Plaintiff "must show that the product either was not built to specifications or did not conform to the manufacturer's intended design," Williamson, supra, 2013 WL 3833081, at *4; Miccio, supra, 224 F. Supp. 3d at 204. "In other words, a manufacturing flaw exists when the unit in question deviates in quality and other performance standards from all of

the other identical units," Bertini v. Smith & Nephew, Inc., 8 F. Supp. 3d 246, 257 (E.D.N.Y. 2014); Miccio, supra, 224 F. Supp. 3d at 204.

For an alternative design defect claim, "a plaintiff must demonstrate: '(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing Plaintiff's injury,'" Thomas, supra, 2021 WL 1176011, at *2 (quoting Oden v. Boston Sci. Corp., 330 F. Supp. 3d 877, 888 (E.D.N.Y. 2018) (denying dismissal of design defect claim)) (Docket No. 37, Arthrex Memo. at 6; see also Docket No. 18, TE Memo. at 6).

Ordinarily, to state a design defect claim Plaintiff must allege that the device met all design specifications but a manufacturing claim requires proof of deviation from the design specifications. Those two concepts are mutually exclusive, Astoria Energy II LLC v. HH Valves Ltd., No. 17CV5724, 2019 WL 4120759, at *4 (E.D.N.Y. Aug. 2, 2019) (Reyes, Mag. J.) (Report & Recommendation), adopted, 2019 WL 4091417 (E.D.N.Y. Aug. 29, 2019); Thomas, supra, 2021 WL 1176011, at *3. At the pleading stage, however, a claimant may allege in the alternative manufacturing and design defects, Catalano v. BMW of N. Am., LLC, 167 F. Supp. 3d 540, 555 (S.D.N.Y. 2016); Thomas, supra, 2021 WL 1176011, at *3.

A manufacturer's duty to warn is distinct from any duty of care. The duty to warn arises when a manufacturer knows or should have known of a danger arising from a foreseeable use of the product, Liriano v. Hobart Corp., 92 N.Y.2d 232, 237, 677 N.Y.S.2d 764, 766 (1998); Rastelli v. Goodyear Tire & Rubber Co., 79 N.Y.2d 289, 297, 582 N.Y.S.2d 373, 376 (1992) (citing cases). Manufacturers thus have "a duty to warn

against latent dangers resulting from foreseeable uses of its products of which it knew or should have known," Rastelli, supra, 79 N.Y.2d at 297, 582 N.Y.S.2d at 376.

To allege a failure to warn claim, plaintiff "'must show: (1) that a manufacturer has a duty to warn; (2) against dangers resulting from foreseeable uses about which it knew or should have known; and (3) that failure to do so was the proximate cause of harm,'" Thomas, supra, 2021 WL 1176011, at *3 (quoting Quintana v. B. Braun Med. Inc., No. 17-CV-6614 (ALC), 2018 WL 3559091, at *5 (S.D.N.Y. July 24, 2018)) (Docket No. 37, Arthrex Memo. at 7). A failure to warn liability may exist where there was no warning given by a manufacturer, Liriano, supra, 92 N.Y.2d at 237, 677 N.Y.S.2d at 766; see Codling v. Paglia, 32 N.Y.2d 330, 342, 345 N.Y.S.2d 461, 469-70 (1973).

Plaintiff also needs to claim that the warning was inadequate, Ainette v. Market Basket Inc., No. 19cv4506, 2021 WL 1022590, at *13 (S.D.N.Y. Mar. 16, 2021) (Docket No. 37, Arthrex Memo. at 7); Reed v. Pfizer, Inc., 839 F. Supp. 2d 571, 575 (E.D.N.Y. 2012). Adequacy of notice, even when none was given, is an issue of fact, Oliver v. N.L. Indus., Inc., 170 A.D.2d 959, 959, 566 N.Y.S.2d 128, 129 (4th Dep't 1991). A failure to warn claim does not prevail "if a plaintiff does not plead facts indicating how the provided warnings were inadequate," Reed, supra, 839 F. Supp. 2d at 575 (citing cases); see Ainette, supra, 2021 WL 1022590, at *13 (liability could be imposed for a complete failure to warn of a particular hazard, quoting DiMura v. City of Albany, 239 A.D.2d 828, 829, 657 N.Y.S.2d 844, 846 (3d Dep't 1997)). These elements are the same for a negligence product liability claim Based upon a failure to warn as for the distinct failure to warn claim.

The March 2023 Decision dismissed Greenwood's warranty claims, Greenwood March 2023 Decision, supra, 2023 WL 2457070, at *9, and she did not raise them in her Fourth Amended Complaint.

Given the overlap of the strict liability and failure to warn allegations in the Second and Third Causes of Action and product liability negligence asserted in the First Cause of Action, this Court next considers the substance of the amended Second Cause of Action then the Third Cause of Action, concluding with consideration of negligence alleged in the amended First Cause of Action.

D. Second Cause of Action, Strict Product Liability

1. Parties' Contentions

Arthrex argues that the Second Cause of Action should be dismissed with prejudice because despite her amendment Greenwood failed to plead a manufacturing defect theory of Arthrex's strict liability (Docket No. 51, Def. Memo. at 4-6). Without alteration, Greenwood repeats her prior allegations from her Third Amended Complaint in the Fourth Amended Complaint (id. at 6). By not changing these allegations, the deficiencies in Greenwood's manufacturing defect claim remain unaddressed (id.).

As for Greenwood's alternative design defect claim stated, Arthrex argues that this Court should consider anew this claim as raised in the amended pleading (id. at 1, 6). Arthrex points to Greenwood's continued reliance upon Arthrex's recall notice of January 2019 which was issued months after the use of the Arthrex Burr device upon Plaintiff in October 2018. Arthrex concludes this recall does not provide grounds for any warning to Plaintiff and paragraph 30 of the Fourth Amended Complaint does not plead

facts establishing a reasonable alternative design to the Arthrex Burr device used upon Greenwood. (Id. at 8-9.)

Greenwood states her theory that Arthrex represented that the Arthrex Burr device could withstand elevated temperatures when used in surgical procedures but a mechanical malfunction caused the device used on her to overheat excessively (Docket No. 54, Pl. Memo. at 3-4). Plaintiff argues she also alleged design defect and failure to warn in her Second Cause of Action (consistent with the prior Decision in this case) (id. at 6-7, citing Greenwood March 2023 Decision, supra, 2023 WL 23457070, at *6). Greenwood also claims she sufficiently alleged her new Third Cause of Action with the amendment of ¶ 40 (id. at 7-8) and her allegation of a no warning theory (id. at 8-9).

In reply, Arthrex urges dismissal with prejudice of the Second Cause of Action because Greenwood realleged these claims without alteration (Docket No. 55, Def. Reply Memo. at 3-4). Arthrex concludes that her silence to Arthrex's present objection is a concession to dismissal of that claim (id. at 4, citing, e.g., Smith v. Riccelli Brokerage Servs., LLC, No. 09CV230, 2011 WL 2007209, at *5 (W.D.N.Y. May 23, 2011) (Skretny, C.J.)). Next, Arthrex reaffirms that Plaintiff failed to allege an alternative design to state her design defect claim (id. at 5-6). Arthrex argues that Paragraphs 29 and 30 of the Fourth Amended Complaint (repeating allegations from the Third Amended Complaint) still fail to plead facts of a feasible safer design, as found by this Court for the Third Amended Complaint (id. at 6, citing Greenwood Marc 2023 Decision, supra, 2023 WL 2457070, at *2; Greenwood June 2022 Decision, supra, 2022 WL 2117763, at *12).

2. Second Cause of Action, Manufacturing and Design Defect

In the Second Cause of Action, Greenwood repeats her previous allegations that purports to allege Arthrex's strict liability for design or manufacturing defects in the Arthrex Burr device (Docket No. 49, 4th Am. Compl. ¶¶ 21-34, compare Docket No. 46, 3d Am. Compl. ¶¶ 21-34). Each facet of this claim is considered, given the alternative allegation of design and manufacturing defect claims, see Catalano, supra, 167 F. Supp. 3d at 555.

a. Greenwood Does Not Allege Design Defect Liability

Although the present Second Cause of Action alleges possible design flaws and shows a causal connection between that defect and her injuries, see Rosen v. St. Jude Med., Inc., 41 F. Supp. 3d 170, 183 (N.D.N.Y. 2014), Arthrex argues that this claim fails to show the feasibility of alternative designs (Docket No. 51, Def. Memo. at 10-13; Docket No. 55, Def. Reply Memo. at 5-6). Paragraph 30 of the Fourth Amended Complaint repeats the allegation in the Third Amended Complaint (compare Docket No. 49, 4th Am. Compl. ¶ 30 with Docket No. 46, 3d Am. Compl. ¶ 30; see also Docket No. 55, Def. Reply Memo. at 5 (arguing the repetition of this claim)) that a feasible alternative design was "self-evident" without alleging an alternative.

Upon further reflection, a declaration of self-evident feasibility is not sufficient to allege safer alternatives (see also Docket No. 55, Def. Reply Memo. at 5-6). Self-evident alternatives presume knowledge of those obvious alternatives. Greenwood needs to allege more than Arthrex could manufacture a device that would not overheat or malfunction in operation. Greenwood fails to allege an example of this "self-evident" safer design. By not alleging the defects in the Arthrex Burr, what led it to overheat, or allege safer alternatives, Greenwood fails to establish feasible alternatives to allege a defective

design claim. Without presenting an example of this "self-evident" option, the feasibility of that option cannot be assessed. Greenwood's essentially unamended allegation merely restates that a safer device could have been made but it fails to state what such a device looks like or how it would function. The earlier Decisions, e.g., Greenwood March 2023 Decision, supra, 2023 WL 23457070, at *6, did not consider Greenwood's failure to present feasible alternatives. This Court now concludes that the declaration of self-evidence in the Fourth Amended Complaint here does not state feasible alternative design to allege a design defect claim.

Plaintiff's design defect claims in the Fourth Amended Complaint really were not amended and thus does not survive Arthrex's Motion to Dismiss (Docket No. 51); that Motion dismissing the Second Cause of Action is granted.

b. Greenwood Still Fails to Allege Manufacturing Defect in this Pleading

"A manufacturing defect claim should be dismissed if the plaintiff has not alleged that 'the particular [product] administered to her had a defect compared to other samples of that [product],'" Bertini, supra, 8 F. Supp. 3d at 257 (citing Reed, supra, 839 F. Supp. 2d at 577); Miccio, supra, 224 F. Supp. 3d at 204. Greenwood again repeats (without alteration) her Third Amended Complaint allegations of manufacturing defect claims in her Fourth Amended Complaint. The Fourth Amended Complaint generically alleges a manufacturing defect (Docket No. 49, 4th Am. Compl. ¶ 24; see Docket No. 46, 3d Am. Compl. ¶ 24), that Arthrex negligently released a malfunctioning device used in her surgery despite the existence of other, properly manufactured Arthrex Burr devices (Docket No. 49, 4th Am. Compl. ¶ 15). Greenwood here claims that Arthrex failed to test properly the device or use appropriate alloys and insulation causing her injury (id. ¶ 32).

This amended allegation, however, still does not compare the device used in her surgery with other Arthrex Burr devices (beyond claiming that the device used on her somehow malfunctioned, id. ¶ 15), specify the purported malfunction, or allege any deviation from design specifications (see Docket No. 43, Arthrex Reply Memo. at 9; see also Docket No. 37, Arthrex Memo. at 5, citing Greenwood June 2022 Decision, supra, 2022 WL 2117763, at *12, Bertini, supra, 8 F. Supp. 3d at 249-50, 257).

As previously alleged, these allegations still focus more on the design defect in the Arthrex Burr device generally and not any deviation of one device from others manufactured by Arthrex. Greenwood does not plausibly allege a difference between the device used on her from other Arthrex Burr devices. Despite the Fourth Amended Complaint, Greenwood concludes that the Arthrex Burr device used in her surgery malfunctioned without stating the exact malfunction or speculating upon a cause or theory for the malfunction.

Greenwood here reasserts previous allegations where she only alleges the failure of testing in general (Docket No. 49, 4th Am. Compl. ¶¶ 32-33; see Docket No. 46, 3d Am. Compl. ¶¶ 32-33) without detailing how the device failed, the type of testing that should have been performed, whether the device used on Plaintiff was tested, or what testing was performed on other units of the Arthrex Burr device. Greenwood still has not alleged what occurred with other Arthrex Burr devices as compared with the device used in her surgery. As a result, the Fourth Amended Complaint also fails to state a manufacturing defect claim.

Furthermore, Greenwood still has not alleged the manufacturing process for the Arthrex Burr device used in her surgery to allege such a defect or any physical differences

between these units and the device used in her surgery. Absent allegation of sampling or additional information about manufacturing Arthrex Burr devices, Greenwood's manufacturing defect claims as alleged unchanged in the Fourth Amended Complaint fail to state a claim.

c. Further Leave to Amend Is Denied

Greenwood was given opportunities to amend her manufacturing and design defect claims as alleged in her Third Amended Complaint. She could have alleged a comparison of the Arthrex Burr device used on her compared with others Arthrex manufactured or sampling of Arthrex devices. She, however, has not done so. Instead, she repeated her earlier, insufficient allegations. Failing to cure defects in the earlier versions of this Cause of Action after being afforded multiple attempts to do so, such an amendment going forward would be futile, Sauer v. Xerox Corp., 173 F.R.D. 78, 80 (W.D.N.Y. 1997) (Larimer, C.J.) (failure to plead case after sufficient opportunity to do so after receiving leave to amend is by itself sufficient grounds to deny further leave); 6 Charles A. Wright, Arthur R. Miller and Mary Kay Kane, Federal Practice and Procedure § 1487, at 746 (Civil ed. 2010).

Therefore, Arthrex's Motion to Dismiss the Second Cause of Action (Docket No. 51) is granted dismissing her alternative manufacturing defect and design defect claims, with prejudice.

E. Third Cause of Action, Duty to Warn

Next, the Third Cause of Action of the Fourth Amended Complaint generally alleges failure to warn (Docket No. 49, 4th Am. Compl. ¶ 44). As with her other amended

allegations, Greenwood generally repeats her Third Amended Complaint allegations of her failure to warn claims (cf. Docket No. 46, 3d Am. Compl. ¶¶ 43-47).

1. Parties' Contentions

Arthrex reiterates that Greenwood fails to allege an insufficient warning theory for her new Third Cause of Action (Docket No. 51, Def. Memo. at 11-12). Arthrex now argues that Greenwood has not alleged a no warning claim and lacks "a Rule 11 basis for such a theory" (id. at 13) or fails to plead a no warnings claim (id. at 14). Arthrex claims that the only new factual allegation, the cutting of flesh and bone during surgery with the Arthrex Burr device has a potential for overheating (Docket No. 49, 4th Am. Compl. ¶ 40), was suggested by this Court's last Decision, Greenwood March 2023 Decision, supra, 2023 WL 2457070, at *10, but that allegation lacks sufficient facts to plead the claim beyond her conclusory allegations (Docket No. 51, Def. Memo. at 15-16).

Greenwood now claims she sufficiently alleges her failure to warn claim based upon Arthrex failed to warn despite the obvious risk posed by the Arthrex Burr device (Docket No. 54, Pl. Memo. at 7-9).

In reply, Arthrex urges dismissal of the amended Third Cause of Action with prejudice because Greenwood fails either to plead an insufficient warning or no warning theory (Docket No. 55, Def. Reply Memo. at 8-9, 9-10). Furthermore, Arthrex argues that Greenwood has not addressed the warning Arthrex gave for the Arthrex Burr in alleging a no warning theory (id. at 10). Arthrex offers that the alleged potential risk for overheating (cf. Docket No. 49, 4th Am. Compl. ¶ 40) was not sufficient to establish the need for warning (Docket No. 55, Def. Reply Memo. at 10).

2. Greenwood Fails to Allege Arthrex's Duty to Warn in the Pending Complaint

Greenwood repeats her earlier allegation (see Docket No. 46, 3d Am. Compl. ¶¶ 43-47) that Arthrex insufficiently warned the dangers of the Arthrex Burr device (Docket No. 49, 4th Am. Compl. ¶¶ 36-41). The only change from the Third Amended Complaint is ¶ 40 alleging the potential for overheating from the use of the Arthrex Burr device. As Arthrex argues (Docket No. 51, Def. Memo. at 11-12), Greenwood still has not alleged an alternative warning that Arthrex should have furnished. She further does not argue that she alleged an insufficient warning by presenting an alternative. Thus, Greenwood, fails to plead an insufficient warning.

Greenwood purports to allege the alternative theory of the nonexistent warning, see Ainette, supra, 2021 WL 1022590, at *13; Alfieri v. Cabot Corp., 17 A.D.2d 455, 460, 235 N.Y.S.2d 753, 759 (1st Dep't 1962), aff'd, 13 N.Y.2d 1027, 235 N.Y.S.2d 753 (1963), and that the absence of a warning thus being inadequate as a matter of law, see Reed, supra, 839 F. Supp. 2d at 575, rather than requiring Greenwood to allege a better warning. She, however, alludes to a warning given by the manufacturer to her doctor, Dr. Tetro (Docket No. 49, 4th Am. Compl. ¶ 12). According to the chronology here, Dr. Tetro performed surgery with the device on October 25, 2018 (id. ¶ 10). On November 6, 2018, Dr. Tetro told Greenwood about the malfunction identified by the manufacturer. Then in January 2019, Arthrex issued its recall of the device. (Id. ¶¶ 12, 14.) Using the notice to Dr. Tetro alleged in the Fourth Amended Complaint, Greenwood does not present the text of Arthrex's warning that Dr. Tetro obtained (save the doctor's statement). This alleges the existence of some form of warning from Arthrex that precludes her present contention that no warning was offered. Further, Arthrex now raises that it published

warnings (Docket No. 55, Def. Reply Memo. at 9-10) but neither party says when those warnings were given.

Greenwood's amendment at ¶ 40 of the Fourth Amended Complaint purports to cure the pleading omission for the need to warn. There, she claims that the cutting of bone and flesh with the Arthrex Burr inherently caused friction and presented the potential for overheating (Docket No. 49, 4th Am. Compl. ¶ 40) and that the overheating risk was so apparent as to require a warning. This repeats the language from this Court's prior decision listing the omission in the amended pleading, Greenwood March 2023 Decision, supra, 2023 WL 2457070, at *10. However, she only alleges the potential for overheating (again as suggested in that Decision), not the actuality of overheating or how Arthrex would know about this potential that would require Arthrex to warn users.

Further, Greenwood does not allege when Arthrex learned the potential burn risk from the Arthrex Burr device. No one states when Dr. Tetro was advised of the manufacturer's concerns about the device.

Dr. Tetro's November 2018 statement to Greenwood asserts Arthrex's knowledge of the defect to the Arthrex Burr device, raising its obligation to warn. From that statement, the manufacturer had knowledge in November 2018 of the burn risk. This is critical for establishing Arthrex's need to warn users of its device as of November 2018, rather than the January 2019 recall (cf. Docket No. 51, Def. Memo. at 8-9). Greenwood, however, still has not alleged when Arthrex had knowledge of the overheating problem leading up to Plaintiff's October 2018 surgery. It is possible that Arthrex could have learned of the overheating risk after Greenwood's October surgery as well as before that procedure;

Greenwood's own October 2018 surgery may have provided that notice of the harm to Arthrex that the Arthrex Burr device posed.

Plaintiff still speculates as to Arthrex's knowledge of this defect prior to her October 2018 surgery presumably because as manufacturer of the device it should know or learn of such risks. She does not allege when Arthrex discovered this risk or how Arthrex knew the potential for overheating beyond speculation to survive a Motion to Dismiss under Twombly, supra, 550 U.S. at 555.

Upon these amended allegations, the Third Cause of Action of the Fourth Amended Complaint fails to state a claim of a failure to warn. The next issue is whether Greenwood can amend her failure to warn claim further to state a claim.

3. Further Leave to Amendment of this Claim Is Denied

Unlike a prior Decision, this Court now finds that Greenwood was given many opportunities to amend the present amended Third Cause of Action to allege her failure to warn claim but did not do so. Instead, she repeated her earlier allegations and added the bare allegation (suggested by the Decision dismissing the claim in the earlier version of the Complaint) that the cutting of bone and flesh during surgery causes friction and poses the potential for overheating (Docket No. 49, 4th Am. Compl. ¶ 40) without more.

Given the opportunities to so amend, such an amendment of a duty to warn claim has proven to be futile. Greenwood is denied leave to file a further Amended Complaint to amend this Third Cause of Action. Arthrex's Motion to Dismiss (Docket No. 51) this Third Cause of Action in the Fourth Amended Complaint is granted with prejudice.

With the interaction of the failure to warn and the design defect theories for a product liability negligence claim, this Court next concludes with consideration of the First Cause of Action for product liability negligence.

F. First Cause of Action, Negligence

1. Parties' Arguments

Greenwood responds that she alleged Arthrex's negligence in her First Cause of Action upon her theory that the Arthrex Burr device malfunctioned and overheated when used as designed for surgery (Docket No. 54, Pl. Memo. at 3-4) and resting upon the prior Decision on the negligence claim alleged in the Third Amended Complaint (id. at 6; cf. Greenwood March 2023 Decision, supra, 2023 WL 2457070, at *6).

Arthrex waives its objections to the amended First Cause of Action (Docket No. 53; see also Docket No. 54, Pl. Memo. at 3, 6). In its Reply, Arthrex suggests that this Court sua sponte revisit the March 2023 Decision, Greenwood March 2023 Decision, supra, 2023 WL 2457070, at *5-6, which concluded that Plaintiff stated a First Cause of Action and reconsider the First Cause of Action (Docket No. 55, Def. Reply Memo. at 1, 7). There, Arthrex suggests that this Court clarify whether the First Cause of Action can proceed on a manufacturing defect theory of product liability despite Greenwood inadequately pleading that theory (id.).

2. Greenwood Fails to Allege Negligence

Greenwood repeats unchanged her negligence allegations from the Third to Fourth Amended Complaint (compare Docket No. 46, 3d Am. Compl. ¶¶ 4-19 with Docket No. 49, 4th Am. Compl. ¶¶ 4-19).

Under New York law, there are three possible negligence theories for product liability: design defect, manufacturing defect, or failure to warn, e.g., Miccio, supra, 224 F. Supp. 3d at 208. The March 2023 Decision concluded that Greenwood did not plead manufacturing defect or failure to warn claims while holding that she alleged negligence in the Third Amended Complaint, Greenwood March 2023 Decision, supra, 2023 WL 2457070, at *6-7, 10-11, 5-6.

Now considering the absence of a design defect claim (found above), a manufacturing defect claim, or a failure to warn, the three alternative negligence theories thus are not alleged in this case. Since the elements of negligence for product liability are the same as these alternative theories of design defect, manufacturing defect, or failure to warn, Miccio, supra, 224 F. Supp. 3d at 208, the Fourth Amended Complaint also fails to allege negligence. Arthrex's Motion to Dismiss the amended First Cause of Action (Docket No. 51) is granted. As held for the Second and Third Causes of Action, leave to amend the negligence claim is denied.

IV. Conclusion

Considering the Fourth Amended Complaint (Docket No. 49), Leslie Greenwood fails to plead her First Cause of Action of product liability negligence because she fails to allege any of the alternative theories of product liability (design defect, manufacturing defect, or deficient or nonexistent warning) that would state her negligence claim. Arthrex, Inc.'s Motion to Dismiss (Docket No. 51) this claim is granted.

As for the Second Cause of Action alleging a design defect claim, Greenwood repeats her prior, deficient allegations and still has not alleged a feasible alternative design to state that claim. Arthrex, Inc.'s, Motion to Dismiss (id.) these amended claim is

granted. Arthrex's Motion (id.) dismissing Greenwood's amended Second Cause of Action alleging a manufacturing defect is granted because Greenwood merely repeats previous deficient allegations.

Finally, Arthrex's Motion (id.) seeking dismissal of the new Third Cause of Action purporting to allege breach of the duty to warn (either insufficient warning or failure to warn) is granted. Greenwood has not suggested alternative warning language and rests upon the potential for overheating to require any warning. She alternatively alleged some warning given to her doctor precluding a no warning claim.

With dismissal of the three remaining claims, this case is dismissed. With the opportunities afforded to amend her Complaint, granting further leave to amend now is futile. Thus, dismissal of these claims is with prejudice.

V. Orders

IT HEREBY IS ORDERED, that the Motion to Dismiss the Fourth Amended Complaint of Arthrex, Inc. (Docket No. 51), is GRANTED with prejudice.

FURTHER, that the Clerk of Court is directed to CLOSE this case.

SO ORDERED.

Dated: May 19, 2023
Buffalo, New York

s/William M. Skretny
WILLIAM M. SKRETNY
United States District Judge